IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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First Named Inventor	:	Earl Frederick Barrick
Atty. Docket No.	:	GMU-06-002U
Title of the Invention	:	System and Method for Automatic Shape Registration and Instrument Tracking
Art Unit	:	3737
Examiner	:	John Fernando, Ramirez

Mail Stop Appeal Brief – Patents
Commissioner for Patents
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APPEAL BRIEF

In furtherance to the Notice of Appeal filed on July 30, 2009, Applicants are filing an Appeal Brief as a response to Examiner's final rejections in the January 30, 2009 Office Action. Accompanying this Appeal Brief is the fee set forth in 37 C.F.R. § 41.20(b)(2).

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(1) REAL PARTY IN INTEREST

The real party in interest is George Mason Intellectual Properties, Inc., the assignee of record, as indicated in the assignments recorded Sept. 24, 2009 at the United States Patent and Trademark Office on reel/frame 023277/0119, reel/frame 023277/0261 and reel/frame 023277/0378.

(2) RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related Appeal or Interference.

(3) STATUS OF CLAIMS

The claims for appellate review are Claims 1, 3-5, 7-13, 15-17, 26 and 31.

The current status of the claims is as follows:

- Claims 1, 12, 13, 16, 26, and 31 are Independent Claims.
- Claims 2, 6, 14, 18-25, and 27-30 were withdrawn.
- Claims 1, 3-5, 7-13, 15-17, 26 and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vilsmeier et al. (US 6,611,700) in view of Danisch (6,127,672), or non patent literature Measurand Inc.

(4) STATUS OF AMENDMENTS

There is no amendment filed subsequent to the final rejection.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

Computer assisted image guided stereotactic surgery is particularly useful in accurate localization of intracranial vital structures. Computer assisted image guided stereotactic surgery is beneficial in the biopsy and ablation of primary brain tumors, benign and malignant, as well as in many other intracranial procedures using Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Position Emission Tomography (PET) and Single Photon Emissions Tomography (SPECT). An essential capability of and step in the use of computer assisted surgery is registering the computer system and the digitized CT or MRI image data set to the patient in a common frame of reference in order to correlate the virtual CT or MRI image with the actual body section so imaged. [See US 2002/0087101, paras. 0004-06]

The claimed subject matter is directed towards devices and systems for performing surgery or therapeutic interventions on a patient. A basic embodiment includes a first non-invasive curvature sensor with imageable fiducials placed externally on a patient to provide first external curvature data. An attachment fixture is coupled to the first non-invasive curvature sensor. A computer relates curvature data from the first non-invasive curvature sensor to the location of the imageable fiducials and a 3-D internal image set of the patient. (*See* Claim 1)

Prior to an operation, a patient undergoes an imaging study wherein a 3-D internal image set is taken of the portion of the patient's body that will be operated upon. In preparation for this imaging study, the first curvature sensor and fiducials are applied to the patient so that their positions on the body are recorded in the same imaging study. The imaging study data set is processed to locate within a common frame of

reference: the position of the attachment fixture with respect to the patient's internal anatomy to be operated on (defined by the 3-D internal image data set), the non-invasive curvature sensor and the fiducials. (See US 2002/0087101, para. 56)

Additionally claimed embodiments include a second non-invasive curvature sensor coupled to the attachment fixture and terminating with a tool connector. (See Claim 3). During surgery, the computer displays the position and orientation of a surgical tool connected to the tool connector with reference to the patient's internal anatomy without having to otherwise invade the patients' body for imaging purposes. (See Abstract).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3-5, 7-13, 15-17, 26 and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vilsmeier et al. (US 6,611,700) in view of Danisch (6,127,672), or non patent literature Measurand Inc.

(7) ARGUMENTS

Claims 1, 3-5, 7-13, 15-17, 26 and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vilsmeir et al. (US 6,611,700) (herein after Vilsmeier) in view of Danisch (6,127,672) (herein after Danisch), or non patent literature Measurand Inc. (herein after Measurand).

1. It was improper to modify Vilsmeier with either Danisch or Measurand to establish a prima facie case of obviousness under 35 U.S.C. § 103(a) because Danisch or Measurand do not disclose a "3-D internal image set."

The presently claimed invention uses external curvature data to derive a frame of reference for a 3-D internal image set of a patient. This relationship may be used to assist surgery or therapeutic intervention(s) on the patient. Independent claims 1, 12, 13, 16, and 26 contain the limitation to "… relate the curvature of the first non-invasive curvature sensor to the location of the imageable fiducials and a 3-D internal image set of the patient."

Support for this limitation are found in paragraphs 56 through 62 of the published application US 2002/0087101 A1 which states:

> … patient undergoes an imaging study … wherein a 3-D internal image set is taken of the portion of the patient's body … curvature sensor(s) … fiducials and/or an attachment fixture. The imaging study data set is then processed … wherein the computer image processor locates the position

> of the attachment fixture with respect to the patient's anatomy, the fiducials and, if employed, the curvature sensor garment, and calculates their positions and orientations within the image data set. [T]he attachment fixture is marked on the image data set. ... [T]he computer image processing system obtains the 3-D position information from the curvature sensor … [t]hen the computer image processing system calculates the position of the attachment fixture relative to the fiducials … using the known relative positional information of the fiducials to the curvature sensor.

After stating that "Vilsmeier does not explicitly teach a non-invasive curvature sensor that provides external curvature data and a 3D internal image set," the Examiner declared that "medical devices for the application of therapeutics on a patient that has a non-invasive curvature sensor that provides external curvature data and a 3D internal image set, are conventional in the art as evidenced by the teachings of Danisch (6,127,672) and non-patent literature Measurand Inc." (Office Action dated Jan 30, 2009, Pg. 3).

Measurand

The Examiner indicated that the Claim limitation "3D internal image set" is taught by Measurand Inc. (*See* id.). In support of this statement, the Examiner noted that "[i]n the non-patent literature Measurand Inc., uses a fiber optic based 3D bend and twist sensor, that knows where it is continuously along its length, providing accurate position and orientation information, even when in partial or variable

contact with an object or person. It can be used on its own, built into or attached to a structure, or attached to a person to form real-time 3D computer images and collect data corresponding to complex shapes 3-D motion data images are created which later can be edited using software that relates the curvature data with 3D images to create a 3D surface." (Office Action dated Jan. 30, 2009, Pg. 2, Para. 3). However, Measurand only discloses using a sensor to create external 3D surface image sets, whereas, the presently claimed embodiments "… relate the curvature of the first non-invasive curvature sensor to the location of the imageable fiducials and a 3-D internal image set of the patient." (Appl., Claim 1)

Therefore, Applicants assert that the Examiner has not presented a prima facie case of obviousness to support a rejection under **35 U.S.C. § 103(a)** because the Examiner did not show how Measurand teaches a 3D internal image set.

Danisch

With respect to Danisch, the Examiner only discusses how Danish supports using a sensor to provide **external curvature data.** The Examiner specifically stated that Figure 38 in Danisch "illustrate[s] the conventionality of using a non-invasive curvature sensor that provides external curvature data. Additionally, the specification in col. 15 line 63 - col. 16 line 30, discloses the use of a non-invasive curvature sensor in combination with a video display computer. Based on the above observations, for a person of ordinary skill in the art, enhancing a sensor with a non invasive curvature sensor that provides **external curvature data** would have been considered obvious in view of the proven conventionality of this enhancements."

However, Applicant notes that Danisch only discloses using a non invasive curvature sensor to provide **external curvature data**, whereas, the presently claimed embodiments "… relate the curvature of the first non-invasive curvature sensor to the location of the imageable fiducials and a 3-D internal image set of the patient." (Appl., Claim 1).

Therefore, Applicants assert that the Examiner has not presented a prima facie case of obviousness to support a rejection under **35 U.S.C. § 103(a)** because the Examiner did not show how Danisch teaches a 3D internal image set.

2. It was improper to modify Vilsmeier with either Danisch or Measurand under 35 U.S.C. § 103(A) because Vilsmeier teaches away from using external imageable fiducials with an external position sensor

It was improper to modify Vilsmeier with either Danisch or Measurand under 35 U.S.C. § 103(A) because Vilsmeier, the Examiners primary reference, teaches away from using external imageable fiducials with an external position sensor. Where a reference teaches away from the claimed invention, a *prima facie* case of obviousness may not be established by the examiner. See MPEP §2144.05 (showing that a *prima facie* case of obviousness may be rebutted by the applicant by showing that the art teaches away from the claimed invention.)

The Examiner stated that the limitations "externally" and "imageable fiducials coupled to the first curvature sensor" are insufficient to overcome the prior art references. Applicant disagrees. Vilsmeier specifically teaches against the external

use of fiducial markers in column 1, lines 35 to 54. The first sentence in this section explicitly states that "**using markers arranged on the skin surface … involves problems**." To delve further into the teachings of Vilsmeier, Applicant would like to recite several quotes from the two sections of the Vilsmeier specification that the Examiner cited (and copied for emphasis). First, Vilsmeier column 2, line 33 recites that "the position sensor is **inserted into the body**." Second, Vilsmeier column 2, lines 38 – 42 recites that the "position sensor may be firmly anchored or fixed in place … by means of supporting or clamping elements externally movable at **the inserted position sensor**." Third, Vilsmeier column 2, lines 38 – 42 discusses irradiating a site "[o]nce such a position sensor has been **inserted in the body**." In fact, Vilsmeier specifically teaches against the external use of fiducial markers in column 1, lines 35 to 54. For these reasons, Applicant believes that the claimed invention overcomes Vilsmeier as a prior art reference.

Therefore, Applicant asserts that the Examiner has not presented a valid case of obviousness to support a rejection under 35 U.S.C. § 103(a) because Vilsmeier, the Examiners primary reference, teaches away from using external imageable fiducials with an external position sensor.

(8) CLAIMS APPENDIX

See infra Appendix A.

(9) EVIDENCE APPENDIX

See infra Appendix B.

(10) RELATED PROCEEDINGS APPENDIX

There are no related proceedings applicable in this case.

(11) CONCLUSION

In view of the arguments and authorities presented above, Applicants request the Board to reverse the Examiner's 35 U.S.C. § 103(a) rejections and allow the application.

Applicants hereby authorize the Commissioner to credit or debit any outstanding fees in connection with this patent application using Deposit Account No. 50-3212.

Respectfully submitted,

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APPENDIX A

(8) CLAIMS APPENDIX

Listing of the Claims

Claim 1 (previously presented): A device for performing surgery or therapeutic interventions on a patient, comprising:

a first non-invasive curvature sensor configured to be placed externally on a patient, the first non-invasive curvature sensor providing first external curvature data;

imageable fiducials coupled to the first non-invasive curvature sensor; and

an attachment fixture coupled to the first non-invasive curvature sensor; and

a computer configured to receive the first external curvature data and relate the curvature of the first non-invasive curvature sensor to: the location of the imageable fiducials; and a 3-D internal image set of the patient.

Claim 2 (Cancelled)

Claim 3 (previously presented): The device of claim 1, further comprising:

a second non-invasive curvature sensor providing second external curvature data, the second non-invasive curvature sensor having a first end and a second end and capable of being coupled to the attachment fixture at the first end; and

a tool connector coupled to the second end of the second non-invasive curvature sensor.

Claim 4 (previously presented): The device of claim 3, further comprising a second

attachment fixture capable of being positioned at a known location with respect to the first non-invasive curvature sensor, wherein the second end of the second non-invasive curvature sensor is coupled to the second attachment fixture and the tool connector is coupled to the second non-invasive curvature sensor between the first end and the second end.

Claim 5 (original): The device of claim 3, further comprising a monitor for positionally displaying the tool connector with respect to the patient.

Claim 6 (cancelled)

Claim 7 (original): The device of claim 3, further comprising an optical tracking system electronically coupled to the computer and configured to positionally track the tool connector or a tool positioned in the tool connector.

Claim 8 (previously presented): The device of claim 7, wherein the computer uses both the second non-invasive curvature sensor and the optical tracking system to positionally track the tool connector or a tool positioned in the tool connector.

Claim 9 (previously presented): The device of claim 1, wherein the computer is configured to determine an attachment fixture-centered frame of reference based on the first external curvature data.

Claim 10 (previously presented): The device of claim 1, wherein the first non-invasive curvature sensor comprises a fiber optic curvature sensor.

Claim 11 (previously presented): The device of claim 1, wherein the attachment fixture comprises:

at least one imageable fiducial; and

a latching mechanism configured for attaching to the first end of the non-invasive second curvature sensor.

Claim 12 (previously presented): A device for performing surgery or therapeutic intervention on a patient, comprising:

an attachment fixture;

at least one imageable fiducial coupled to the attachment fixture, the imageable fiducial being capable of being detected by a medical imaging system;

a non-invasive curvature sensor having a first end and a second end and capable of being coupled to the attachment fixture at the first end, the non-invasive curvature sensor configured to be placed externally on a patient, the non-invasive curvature sensor configured to provide external curvature data ;

a tool connector coupled to the second end of the non-invasive curvature sensor; and

a computer configured to receive the external curvature data and relate the curvature of the first non-invasive curvature sensor to: the location of the imageable fiducials; and a 3-D internal image set of the patient.

Claim 13 (previously presented): A device for use in an image guided therapy or image guided surgery system, comprising:

a non-invasive curvature sensor configured to be applied externally to a portion of a patient, the non-invasive curvature sensor being adapted to measure and provide external curvature data;

imageable fiducials located on the non-invasive curvature sensor;

an attachment fixture coupled to the non-invasive curvature sensor, the attachment fixture comprising an imageable fiducial; and

a computer configured to receive the external curvature data and relate the curvature of the non-invasive curvature sensor to: the location of the imageable fiducials; and a 3-D internal image set of the patient.

Claim 14 (cancelled)

Claim 15 (previously presented): The device for use in an image guided therapy or image guided surgery system according to claim 13, wherein the non-invasive curvature sensor comprises a fiber optic curvature sensor.

Claim 16 (previously presented): A device for generating a patient based frame of reference for an image guided therapy or image guided surgery system, comprising:

a non-invasive curvature sensor configured to be applied externally to a portion of a patient, the non-invasive curvature sensor being adapted to measure and

provide external curvature data of the curvature of the portion of the patient;

imageable fiducials coupled to the non-invasive curvature sensor; and

an attachment fixture coupled to the non-invasive curvature sensor at a known position with respect to the non-invasive curvature sensor; and

a computer configured to receive the external curvature data and relate the curvature of the non-invasive curvature sensor to: the location of the imageable fiducials; and a 3-D internal image set of the patient.

Claim 17 (previously presented): A device for generating a patient-based frame of reference for an image guided therapy or image guided surgery system according to claim 16, wherein each of the imageable fiducials are coupled to the non-invasive curvature sensor at known inter-fiducial distances.

Claim 18 – 25 (cancelled)

Claim 26 (previously presented): A system for monitoring or enabling surgery on a patient at a distance, comprising:

a first non-invasive curvature sensor configured to be placed externally on the patient, the first non-invasive curvature sensor providing first external curvature data;

imageable fiducials coupled to the first non-invasive curvature sensor;

an attachment fixture attached to the first non-invasive curvature sensor;

a second non-invasive curvature sensor having a first end and a second end and capable of being coupled at the first end to the attachment fixture, the second

non-invasive curvature sensor providing second external curvature data;

a tool capable of being coupled to the second end of the second non-invasive curvature sensor; and

a computer configured to:

receive the first external curvature data;

receive the second external curvature data;

relate the curvature of the first non-invasive curvature sensor to: the location of the imageable fiducials; and a 3-D internal image set of the patient;

provide an output of the curvature of the first non-invasive curvature sensor and the position and orientation of the tool coupled to the second end of the second non-invasive curvature sensor with respect to the attachment fixture; and

communicate the output of the computer to a distant receiver using a communication device that is electronically coupled to the computer.

Claim 27 – 30 (cancelled)

Claim 31 (previously presented): A device for conducting surgery or therapy on a body, comprising:

means for externally measuring the curvature of a body;

means for locating the position of the means for externally measuring the curvature of a body within a frame of reference;

means for determining the position of a tool with respect to the means for externally measuring the curvature of a body; and

means for registering a 3-D internal image set of the body to the means for externally measuring the curvature of a body.

APPENDIX B

(9) EVIDENCE APPENDIX

References

None